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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/578,587

04/19/2000

Vilmos Keri

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12/09/2003

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/578,587

Applicant(s)

KERI ET AL.

Examiner

Irene Marx

Art Unit

1651

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Irene Marx
Primary Examiner
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The amendment after final filed 11/12/03 is acknowledged. Claims 4, 6, 11-16 are being considered on the merits.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants tout the yield of mevinolin in the examples 2-6 of the specification of 98.8 to 99.7%. However, this is not the invention claimed. The distinction between “treating” at a certain pH and “adjusting” pH to substantially the same level is not clearly delineated. The bald statement regarding the range of 7 to 14.3 is not substantiated with appropriate evidence. On the contrary, applicants acknowledged on this record that Jekkel uses a pH of 10-10.2 (previous Response, page 2, paragraph 7). Also, claim 11 is directed to a pH of **about 7.5 to about 10** to dissolve the mevinolin in step (a) and not to a precise range as implied by the arguments.

The steps of the process “consisting essentially of” steps (a)-(c) are not seen to exclude the use of ion exchange chromatography, since step (b) specifically is directed to “separating the fungal culture medium from the said *Aspergillus* strain to obtain a separated fermentation liquor”. In addition, Applicant’s attempt to distinguish the use of ion exchange chromatography in Jekkel’s Example 2 over the use of precipitation by acidification in the present invention is noted. However, there is no explicit step in the instant claims requiring “precipitation by acidification” to the exclusion of other steps.

With respect to the declaration, Applicants now argue that the Polya declaration presents a side by side preparation of mevinolin according to Example 1 of Jekkel and claim 11. However, the correlation between the declaration and current claim 11 is not clearly delineated. The claims under examination are not directed to a process using the sole strain used in the as-filed specification, i.e., strain *A. obscurus* MV-1 to produce purified mevinolin. The Polya declaration is directed specifically to this strain and provides no information as to the effect(s) of using any strain within the species *A. obscurus* or *A. terreus*. The claims are directed to unidentified strains of *A. obscurus* or *A. terreus*, the mevinolin-producing properties of which are uncertain; makes the use of a solvent optional, and omits process steps critical to obtaining the crystallized product, such as “filtering, redissolving and recrystallizing”, touted in the declaratory evidence.

From the declaration it appears that the favorable results touted in the declaration regarding the absence of contaminants are the result of the combination of the specific mevinolin producing strain cultured, i.e., *A. obscurus* MV-1, and process parameters such as the specific

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use of pH 9 and pH 2 as well as the use of isobutyl acetate as the solvent. This is not the claim designated invention.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejections are deemed proper and are adhered to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 703-308-2922. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0926.



Irene Marx
Primary Examiner
Art Unit 1651